

REMARKS

Claims 1-21 are pending in this application. By this Amendment, claims 1-3 and 8-21 are amended. Support for the amendments to the claims may be found, for example, in the original claims and the specification. Amendments to claims 1-3 and 8-21 were made to improve the clarity of the claims and to better conform to U.S. practice, and not for reasons relating to patentability. No new matter is added.

In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

I. Rejection under 35 U.S.C. §112, Second Paragraph

The Office Action rejects claims 11, 16, 20, and 21 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11

The Office Action rejects claim 11 as allegedly lacking antecedent basis. In particular, the Office Action asserts that "A plain reading of this language suggests that the compound of general formula II is Boc anhydride or Boc carbamate, although this clearly would not result in the desired product of formula (I). Further claim 11 recites Boc only as one option for R4, not as an essential element, and makes no reference to "the" Boc protecting group. The meaning of claim 11, therefore, cannot be reasonably interpreted." *See* Office Action, page 3, no. 5.

By this Amendment claim 11 is amended to clarify that "the Boc protecting group has been reacted with Boc anhydride or Boc carbamate," thereby obviating the rejection. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claim 16

The Office Action rejects claim 16 as allegedly lacking antecedent basis. In particular, the Office Action asserts that “claim 16 recites “the quinine used in Step B” of claim 1. However claim 1 makes reference only to a benzoquinone, not quinine....therefore, Applicants’ intent is unclear, such that claim 16 is unsolubly ambiguous and cannot be interpreted in any meaningful way.” *See* Office Action, page 3, no. 6.

By this Amendment claim 16 is amended to clarify that “the benzoquinone used [in step (B)],” thereby obviating the rejection. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Claims 20 and 21

The Office Action rejects claims 20 and 21 for recitations “polymorphic forms I and II” as allegedly unclear because “they are not defined in the specification or in the literature relating to its synthesis....” *See* Office Action, page 4, first paragraph.

By this Amendment, claims 20 and 21 are amended to delete the recitations “polymorphic forms I and II,” thereby obviating the rejection. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

II. Rejections Under 35 U.S.C. §103

A. Bhattacharya in view of King and Tsuji

The Office Action rejects claims 1-3, 5-7, 9, 12-14, and 16-19 under 35 U.S.C. §103(a) over EP Application no. 0 298 652 to Bhattacharya et al. ("Bhattacharya ") in view of U.S. Patent No. 5,091,534 to King et al. ("King") and Tsuji et al., *Tetrahed. Lett.* 25 (42), pp. 4783-4786 (1984) (“Tsuji”). Applicants respectfully traverse the rejection.

One of the criteria that must be met to establish a *prima facie* case of obviousness is that the applied references, either separately or combined, must teach or suggest all of the claimed features. *In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The claimed invention is directed to the introduction of a specific protecting group and the subsequent reaction with in the presence of a dehydrogenation catalyst in combination with an optionally substituted compound as defined in step B of claim 1.

In particular, claim 1, as amended requires that “the compound obtained [in step (A)] is reacted in the presence (i) of a dehydrogenation catalyst selected from compounds of group VIII of the Periodic Table of Elements and in the presence of (ii) optionally substituted benzoquinone, allyl methyl carbonate, allyl ethyl carbonate and/or allyl propyl carbonate, and the Δ^1 double bond is introduced in the 1-/2-position...” Emphasis added. Bhattacharya fails to teach or suggest such features. King and Tsuji alone or in combination do not cure the deficiencies of Bhattacharya.

Bhattacharya discloses a method for the production of α β -unsaturated lactams from the corresponding saturated lactams by reacting the saturated compound with a silylating agent and then with a quinone. In particular, Bhattacharya is directed to “the process of the invention involves treatment of the saturated stating lactam, lactone or azasteroid with a silyating agent in the presence of a quinone.” See page 6, lines 4-6. Nowhere does Bhattacharya teach or suggest a dehydrogenation catalyst, as required by claim 1.

King refers to a single pot trialkylsilyl trifluoromethanesulfonate mediated process derivatives of 4-aza-sketo-steroids. See Abstract. King does not teach or suggest anything about the process as claimed in the present invention. Applicants submit that King is irrelevant to the claimed invention.

Furthermore, the Office Action acknowledges that Bhattacharya and King, alone or in combination fails to teach or suggest a dehydrogenation catalyst. However, the Office Action cites Tsuji for its alleged disclosure of a dehydrogenation catalyst.

The Examiner's assertion that Tsuji cures the deficiencies of Bhattacharya and King relies on two considerations: (1) that lactam compounds are considered chemically equal to ester compounds and that (2) the reaction of saturated ester compounds can simply be applied to amide compounds. Applicants respectfully submit that these allegations are incorrect.

In particular, lactam compounds and ester compounds are two different classes of compounds having very different properties. The lactam group and the ester group have different polarities and yield entirely different chemical reactions, as is known to one skilled in the art. To combine or to set equal the properties of these two classes of compounds in a general manner is simply not allowable. Accordingly, one of ordinary skill in the art would have no reason to believe that a lactam group and an ester group compound would react in the same way or be useful for the same purposes. In fact, one of ordinary skill in the art would have the opposite expectation given the different polarities, i.e. yielding entirely different chemical reactions. Accordingly, it cannot be summarily concluded that an ester group and a lactam group would function in the same way in any environment. This is especially so given the well-established unpredictability of chemical compounds. In particular, the behavior of molecules and their reactions are highly unpredictable. As such, a *prima facie* case of obviousness cannot be sustained on the basis of predictable results with respect to the cited combination of references. See *KSR International Co. v. Teleflex Inc., et al.*, 82 U.S.P.Q.2d 1385, 1395-97 (2007) (emphasizing the importance of predictability is important in establishing a *prima facie* case of obviousness); see also M.P.E.P. §2143A.

Moreover, Applicants submit that Tsuji also teaches away from the claimed invention. Although, Tsuji teaches the combinations of an oxidizing agent with a dehydrogenation catalyst,

the dehydration catalyst of Tsuji is specifically for ester compounds. Tsuji refers specifically to the production of α β -unsaturated ester compounds by introducing a double bond into the α β -position to the ester group, whereby the ester group [-C(O)O-Alkyl] has an important function within the reaction sequence. *See* page 4783 (reaction scheme).

Applicants submit that modifying Tsuji to function with an amide would destroy the specific intent, function and purpose of Tsuji because according to the scheme presented on page 4782, the reaction of Tsuji can function **only with an ester group** but **not with an amide group** as the amide group possibly formed [-C(O)NH-Alkyl] would contain a reactive group [-NH-Alkyl] and would not yield the double bond in α β -position to the amide group. Emphasis added. Thus, Tsuji teaches away from the claimed invention.

For at least the reasons mentioned above, claim 1 would not have been rendered obvious by Bhattacharya, King and Tsuji. Claims 1, 3, 5-7, 9, 12-14, and 16-19 variously depend from claim 1 and, thus, also would not have been rendered obvious by Bhattacharya, King and Tsuji. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

B. Bhattacharya in view of King and Tsuji and further in view of Rassmusson

The Office Action rejects claims 1-4 under 35 U.S.C. §103(a) over Bhattacharya in view of King and Tsuji and further in view of U.S. Patent No. 4,760,071 to Rassmusson et al. ("Rassmusson"). Applicants respectfully traverse the rejection.

For at least the reasons mentioned above, independent claim 1 would not have been rendered obvious by Bhattacharya, King, Tsuji. Rassmusson fails to cure the deficiencies of Bhattacharya, King, Tsuji.

Rassmusson refers to novel 17-beat-N(monosubstituted)-carbamoyl-4-aza-5 α -androst-1-en-3-one compounds using benzene-selenic anhydride as a dehydrogenating agent.

See col. 3, lines 67-68. Nowhere does Rasmusson teach or suggest a dehydrogenation catalyst or the other features of the independent claim 1. Nowhere does Rasmusson provide any suggestion or indication to the process as claimed in the present invention.

Accordingly, claim 1 would not have been rendered obvious by Bhattacharya, King, Tsuji, and Rasmusson. Claims 2–4 depend from claim 1 and, thus, also would not have been rendered obvious by Bhattacharya, King, Tsuji, and Rasmusson. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

C. Bhattacharya, King, Tsuji, and Wakselman

The Office Action rejects claims 1, 8, and 11 under 35 U.S.C. §103(a) over Bhattacharya in view of King, Tsuji and further in view of Wakselman, *Encyclopedia of Reagents for Organic Synthesis*, 2001. ("Wakselman"). Applicants respectfully traverse the rejection.

For at least the reasons mentioned above, independent claim 1 would not have been rendered obvious by Bhattacharya, King, Tsuji. Wakselman fails to cure the deficiencies of Bhattacharya, King, Tsuji. Wakselman is cited for the dependent features of claim 15. Despite its asserted disclosure, Wakselman fails to cure the deficiencies of Bhattacharya, King, Tsuji.

Wakselman is cited for its disclosure of an "addition of Boc as a protective group." The claimed invention requires the use of a particular compound in combination with a dehydration catalyst and with an amide. Nowhere does Wakselman teach or suggest such features.

Accordingly, claim 1 would not have been rendered obvious by Bhattacharya, King, Tsuji, and Wakselman. Claims 8 and 11 depend from claim 1 and, thus, also would not have been rendered obvious by Bhattacharya, King, Tsuji, and Wakselman. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

D. Bhattacharya, King, Tsuji, and '366

The Office Action rejects claims 1 and 10 under 35 U.S.C. §103(a) over Bhattacharya, King, Tsuji and further in view of EP Application No. 0 428 366 to King et al. ("366"). Applicants respectfully traverse the rejection.

For at least the reasons mentioned above, independent claim 1 would not have been rendered obvious by Bhattacharya, King, Tsuji. '366 fails to cure the deficiencies of Bhattacharya, King, Tsuji. Despite its asserted disclosure, '366 fails to cure the deficiencies of Bhattacharya, King, Tsuji.

'366 refers to a process comprising treating a selected amide compound with oxalyl chloride, brominating the compound and eliminating the bromine to yield an α β -unsaturated amide. Nowhere does '366 refer to using a dehydrogenation catalyst in combination with a compound, as claimed in the present invention. Therefore, '366 fails to cure the deficiencies of Bhattacharya, King, Tsuji.

Accordingly, claim 1 would not have been rendered obvious by Bhattacharya, King, Tsuji, and '366. Claim 10 depends from claim 1 and, thus, also would not have been rendered obvious by Bhattacharya, King, Tsuji, and '366. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

E. Bhattacharya, King, Tsuji, and further in view of Blaser

The Office Action rejects claim 15 under 35 U.S.C. §103(a) over Bhattacharya, King, Tsuji, and further in view of U.S. Patent No. 4,335,054 to Blaser et al. ("Blaser"). Applicants respectfully traverse the rejection.

As mentioned above, independent claim 1 would not have been rendered obvious by Bhattacharya, King, Tsuji. Blaser is cited for the dependent features of claim 15.

Blaser refers to an entirely different group of compounds, primarily α –unsaturated ester compounds. Despite its asserted disclosure, Blaser fails to cure the deficiencies of Bhattacharya, King, and Tsuji.

Therefore, independent claim 1 would not have been rendered obvious by Bhattacharya, King, Tsuji, and Blaser. Claim 15 depends from claim 1 and, thus, also would not have been rendered obvious by Bhattacharya, King, Tsuji, and Blaser. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

III. Conclusion

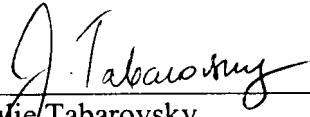
In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the application are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

No fees are believed to be due with regard to this communication. The Commissioner, however, is hereby authorized to charge payment of any fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. §1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. §1.136.

Application No. 10/521,421
Amendment and Response dated May 18, 2009
Reply to Office Action of February 18, 2009
Docket No. 753-45 PCT/US
Page 16

Respectfully submitted,



Julie Tabarovsky
Registration No. 60,808

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700